Claims

1. A medical device comprising a bio-compatible polymeric product with a layered structure comprising
   - at least one upper layer of a first polymeric component,
   - a middle layer of a second polymeric component, and
   - at least one lower layer of a third polymeric component,

   wherein the chain length of the first polymeric component and the third polymeric component is longer than the chain length of the second polymeric component.

2. The medical device according to claim 1, wherein the first polymeric component and the third polymeric component is above 100 monomer units, such as above 1000 monomers units, for example above 10000 monomer units, preferable above 20000 monomer units, more preferable above 30000 monomer units, further preferable above 40000 monomer units, yet further preferable above 50000 monomer units, most preferable above 60000 monomer units.

3. The medical device according to any of the claims 1-2, wherein the first polymeric component is selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, polypropylene, polyethylene oxides and polyvinylpyrrolidon.

4. The medical device according to any of the preceding claims, wherein the second polymeric component is selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, polypropylene, polyethylene oxides and polyvinylpyrrolidon.

5. The medical device according to any of the preceding claims, wherein the third polymeric component is selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, polypropylene, polyethylene oxides and polyvinylpyrrolidon.

6. The medical device according to any of the preceding claims, wherein the first polymeric component and the third polymeric component are substantially identical.

7. The medical device according to any of the preceding claims, wherein the polymeric components comprises a copolymer of polyethylene and/or polypropylene, preferable of polyethylene (PE).

8. The medical device according to any of the preceding claims, wherein the first and third polymeric components are composed of long polymer fibre, and the second polymeric component is a short chain polymer material.

9. The medical device according to any of the preceding claims, wherein the first and third polymeric components are ultra high molecule weight polyethylene (UHMWPE) fibre.

10. The medical device according to any of the preceding claims, wherein at least one upper layer and the at least one lower layer each are composed of at least two layers of polymeric fabric constructed of said first and third polymeric components, and at least one layer of polymeric film, said polymeric film constitutes a layer between two layers of said polymeric fabrics.

11. The medical device according to claim 10, wherein the polymeric components of the middle layer and the polymeric components of the film are substantially identical.

12. The medical device according to any of the claims 10-11, wherein the fabric is produced in a shape suitable for the shape of the medical product

13. The medical device according to any of the claims 10-12, wherein said shape of the fabric is constructed by weave, knit, crochet, plait, interlace, intertwine, interlock, link or unite the fibre in other ways, preferable the fabric is woven or knitted.

14. The medical device according to any of the preceding claims, wherein the UHMWPE fibres in the fabric are crossing each other in intersects which are positioned in angles of 1 to 179 degree, such as in angles of 80 to 100 degree, preferable in angles of about 90 degree.

15. The medical device according to any of the claims 10-14, wherein the first, second and third polymeric components are of medical grade.

16. The medical device according to claim 15, wherein the fabric has a high tensile strength and a high wear resistance.

17. The medical device according to claim 16, wherein the tensile strength of a fibre or strand of the fabric is above1.0 GPa, such as above 1.2 Gpa, preferable above 1.4 Gpa, more preferable above 1.6 Gpa, further preferable above 1.8 Gpa, yet further preferable above 1.9 Gpa, most preferable above 2.0 Gpa,

18. The medical device according to any of the preceding claims, wherein the polymers of the second polymeric component are short chain polymeric material which may be branched.

19. The medical device according to any of the claims 10-18, wherein the film is between 0.001 and 5 mm thick, such as between 0.01 and 5 mm, preferable between 0.1 and 4 mm, more preferable between 0.2 and 3 mm, further preferable between 0.3 and 2 mm, yet further preferable between 0.4 and 1.5 mm, most preferable between 0.5 and 1 mm.

20. The medical device according to any of the preceding claims, wherein the middle layer may be a core, a film or an inlay.

21. The medical device according to any of the claims 20, wherein the core is between 0.1 and 30 mm thick, such as between 0.2 and 25 mm, preferable between 0.3 and 21 mm, more preferable between 0.4 and 17 mm, further preferable between 0.5 and 13 mm, yet further preferable between 0.6 and 10 mm, most preferable between 0.7 and 7 mm.

22. The medical device according to any of the preceding claims, wherein the polymer layers are connected by heating to a temperature between 80 and 250 degree Celsius, such as between 90 and 240 degree Celsius, preferable between 100 and 230 degree Celsius, more preferable between 110 and 220

degree Celsius, further preferable between 120 and 210 degree Celsius, yet further preferable between 130 and 200 degree Celsius, most preferable between 140 and 190 degree Celsius.

23. The medical device according to claim 22, wherein the polymer layers in the connecting process further are subjected to vacuum, such as a vacuum below 500 mbar, preferable below 300 mbar, more preferable below 100 mbar, further preferable below 50 mbar, yet further preferable below 10 mbar, most preferable below 1 mbar.

24. The medical device according to any of the claims 22-23, wherein when heated the polymers of the core or the film or the inlay penetrate into the UHMWPE fibres of the fabrics, and hereby mechanically connect the polymer layers to each other.

25. The medical device according to any of the claims 22-24, wherein the temperature is selected to a level where the fibre of the fabrics are not melted.

26. The medical device according to any of the claims 22-25, wherein the temperature is selected to a level where the main part of the fabrics is not melted, but a thin layer constituting a low number of fibres of the outer part of the outermost fabrics of the polymeric product is melted.

27. The medical device according to any of the preceding claims, wherein the constitution of the polymeric product is: fabric – film – fabric.

28. The medical device according to any of the preceding claims, wherein the constitution of the polymeric product is: fabric – core – fabric.

29. The medical device according to claim 28, wherein one further layer of film and fabric are positioned at each side of the mentioned polymeric product, hereby the constitution of the polymeric product become: fabric – film – fabric – core – fabric – film – fabric.

30. The medical device according to claim 29, wherein one further layer of film and fabric are positioned at each side of the mentioned polymeric product, hereby the constitution of the polymeric product become: fabric – film – fabric – film – fabric – core – fabric – film – fabric – film – fabric.

31. The medical device according to claim 30, wherein one further layer of film and fabric are positioned at each side of the mentioned polymeric product, hereby the constitution of the polymeric product become: fabric – film – fabric – film – fabric – film – fabric – core – fabric – film – fabric – film – fabric – film – fabric.

32. The medical device according to claim 31, wherein one further layer of film and fabric are positioned at each side of the mentioned polymeric product, hereby the constitution of the polymeric product become: fabric – film – fabric – film – fabric – film – fabric – film – fabric – core – fabric – film – fabric – film – fabric – film – fabric – film – fabric.

33. The medical device according to any of claim 20-26, wherein the constitution of the polymeric product is: fabric – film – fabric – inlay – fabric – film – fabric.

34. The medical device according to any of the claims 26-33 wherein a number of film and fabric are positioned at one or both sides of the mentioned polymeric product in a way where film and fabric alternate in the polymeric product.

35. The medical device according to any of the claims 10-26 or 34 wherein the number of fabric and film in said upper layer and in said lower layer is not equal.

36. The medical device according to any of the claims 20-26 or 35, wherein the number of core, film, inlay and fabrics is varied in different areas of the polymeric product.

37. The medical device according to any of the claims 15-26 or 34-36, wherein the number of fabric is between 1 and 100, such as between 2 and 50, for example between 2 and 40, preferable between 2 and 35, more preferable between 2 and 30, further preferable between 2 and 25, yet further preferable between 2 and 20, most preferable between 2 and 10.

38. The medical device according to any of the claims 20-26 or 34-37, wherein the number of film is between 0 and 100, such as between 1 and 50, for example between 1 and 40, preferable between 1 and 35, more preferable between 1 and 30, further preferable between 1 and 25, yet further preferable between 1 and 20, most preferable between 1 and 10.

39. The medical device according to any of the claims 20-26 or 34-38, wherein the number of core is between 0 and 100, such as between 1 and 50, for example between 1 and 40, preferable between 1 and 35, more preferable between 1 and 30, further preferable between 1 and 25, yet further preferable between 1 and 20, most preferable between 1 and 10.

40. The medical device according to any of the claims 20-26 or 34-39, wherein the number of inlays is between 0 and 50, such as between 1 and 40, for example between 1 and 30, preferable between 1 and 25, more preferable between 1 and 20, further preferable between 1 and 15, yet further preferable between 1 and 10, most preferable between 1 and 5.

41. The medical device according to any of the claims 20-26 or 34-40, wherein the polymeric layers in areas or in the entire of some layers has a constitution where film and core or film and inlay are placed towards each other.

42. The medical device according to any of the preceding claims, wherein the shape of the device is any shape which can be formed by pressing into a mould, said shape can constitute a surface which may be but is not limited to flat, curved, waved, undulated, bent, bowed, crooked, while the overall shape of the device may be but is not limited to circular, oval, squared, rectangle, cubed, bowl, cup, crown, cap, basin, preferred shape is cup or hemispherical.

43. The medical device according to any of the preceding claims, wherein to the polymeric material is attached to a component, said component being polymeric or non-polymeric.

44. The medical device according to any of the preceding claims, wherein the device is supplied with one or more apertures, holes, gaps, perforations or hollows.

45. The medical device according to any of the preceding claims, wherein the polymeric product is adapted to be used as a medical device of the body of a mammal, such as a medical device or a prosthesis of the body of a human.

46. The medical device according to any of the preceding claims, wherein the polymeric product is adapted not to interfere with intra-articular components when the device is in the body of a human.

47. The medical device according to any of the preceding claims, wherein said device is utilised to support, bear, carry, replace or displace any constitution within the human body, which comprises high shape stability and good wear resistance.

48. The medical device according to any of the preceding claims, wherein the device completely or substantially completely surrounds an intra-articular component.

49. The medical device according to any of the preceding claims, wherein the device is a hip endoprosthesis.

50. The medical device according to any of the preceding claims, wherein the polymeric product constitutes the surface of a prosthetic device.

51. The medical device according to any of the preceding claims, wherein the device is a cartilage substitute.

52. The medical device according to any of the preceding claims, wherein the device is a breast prosthesis.

53. The medical device according to any of the preceding claims, wherein the device is a stent.

54. The medical device according to any of the preceding claims, wherein the device is a catheter.

55. The medical device according to any of the preceding claims, wherein the device is a heart valve.

56. A method for producing a bio-compatible medical device of a polymeric product, said method comprising

- obtaining a number of at least three polymer layers, comprising
  - at least one upper layer of a first polymeric component,
  - a middle layer of a second polymeric component, and
  - at least one lower layer of a third polymeric component,

  wherein the chain length of the first polymeric component and the third polymeric component is longer than the chain length of the second polymeric component, and
- positioning said polymer layers in a sandwich composition, and
- shaping the sandwich composition of polymer layers by heating said composition followed by pressing it into a mould, where the heating and pressing processes are conducted in vacuum, and
- providing the polymeric product in a desired shape.

57. The method according to claim 56, wherein the at least three polymer layers constitute a core or a film or an inlay with at least one layer of fabric on each side.

58. The method according to claim 57, wherein the core and film and inlay differs in constitution from the fabrics.

59. The method according to any of the claims 57-58, wherein different layers of fabrics have equal constitutions.

60. The method according to any of the claims 57-59, wherein the at least one layer of a first polymeric component or a third polymeric component on each side of the medical device each constitute two or more layers of fabrics, and said two or

more layers of fabrics have a film of a polymer layer or an polymeric inlay in between each fabric.

61. The method according to any of the claims 57-60, wherein the core and the film and the inlay have been constructed by similar polymeric material.

62. The method according to any of the claims 56-61, wherein the polymer layers are composed of a polymer selected from polyacrylates, polystyrene, polyethers, polytetrafluorethylene, polyvinylalcohol, polyethylene, polypropylene, polyethylene oxides and polyvinylpyrrolidon

63. The method according to any of the claims 56-62, wherein the polymer layers are composed of a polymer selected among polyethylene (PE), polypropylene (PP) and polyvinylpyrrolidone (PVP).

64. The method according to any of the claims 56-63, wherein the polymer layers are composed of polyethylene (PE).

65. The method according to any of the claims 56-64, wherein the structure of the fabrics are composed of long polymer fibre, and the core and/or film and/or inlay are composed of short chain polymer material.

66. The method according to any of the claims 56-65, wherein the first and third polymeric component comprises long polymer fibre which are ultra high molecule weight polyethylene (UHMWPE) fibre.

67. The method according to any of the claims 56-66, wherein the fabric is woven into a shape suitable for the shape of the polymeric product.

68. The method according to any of the claims 56-67, wherein the UHMWPE fibres of the fabric in the intersects are positioned in angles of 1 to 179 degree, such as in angles of 80 to 100 degree, such as in angles of about 90 degree.

69. The method according to any of the claims 57-68, wherein the fabric has high tensile strength and high wear resistance.

70. The method according to any of the claims 56-69, wherein the second polymeric component comprises short chain polymer material which are branched.

71. The method according to any of the claims 57-70, wherein the film is between 0.001 and 5 mm thick, such as between 0.01 and 5 mm, preferable between 0.1 and 4 mm, more preferable between 0.2 and 3 mm, further preferable between 0.3 and 2 mm, yet further preferable between 0.4 and 1.5 mm, most preferable between 0.5 and 1 mm.

72. The method according to any of the claims 57-71, wherein the core is between 0.1 and 30 mm thick, such as between 0.2 and 25 mm, preferable between 0.3 and 21 mm, more preferable between 0.4 and 17 mm, further preferable between 0.5 and 13 mm, yet further preferable between 0.6 and 10 mm, most preferable between 0.7 and 7 mm.

73. The method according to any of the claims 57-72, wherein the core or the inlay absorbs shocks, pushes and strokes.

74. The method according to any of the claims 56-73, wherein the heating is of a temperature between 80 and 250 degree Celsius, such as between 90 and 240 degree Celsius, preferable between 100 and 230 degree Celsius, more preferable between 110 and 220 degree Celsius, further preferable between 120 and 210 degree Celsius, yet further preferable between 130 and 200 degree Celsius, most preferable between 140 and 190 degree Celsius.

75. The method according to any of the claims 56-74, wherein the vacuum is below 800 mbar, such as a vacuum below 500 mbar, preferable below 300 mbar, more preferable below 100 mbar, further preferable below 50 mbar, yet further preferable below 10 mbar, most preferable below 1 mbar.

76. The method according to any of the claims 56-75, wherein the shaped product is treated by radiation, to further cross binding the polymers and thereby improving the strength of the product, said radiation may be but is not limited to high-energy electrons, gamma rays, photons, microwaves.

77. The method according to any of the claims 56-76, wherein the shaped product is further subjected to annealing to ensure all linking has appeared.

78. The method according to claim 77, wherein the annealed polymeric product is subjected to surface coating, where the product is coated by polyvinylpyrrolidone (PVP) by plasma polymerisation.

79. The method according to claim 78, wherein the surface coated polymeric product is sterilised by radiation or by heating, where the radiation can be but is not limited to high-energy electrons, gamma rays, photons, microwaves.

80. The method according to claim 75, wherein the shaped polymeric product is subjected to surface coating, where the product is coated by polyvinylpyrrolidone (PVP) by plasma polymerisation.

81. The method according to claim 80, wherein the surface coated polymeric product is crosslinked and sterilised simultaneously by treating with ionizing radiation or by heating.

82. The method according to any of the claims 78-81, wherein the surface coating has a thickness of 1 to 700 nm, such as between 10 and 500 nm, preferable between 20 and 400 nm, more preferable between 30 and 300 nm, further preferable between 40 and 200 nm, yet further preferable between 50 and 100 nm, most preferable between 60 and 90 nm.

83. The method according to any of the claims 56-82, wherein the layered structure of the product is in accordance to the product described in claim 26 to 30.

84. The method according to any of the claims 56-83, wherein the shape and size of the polymeric product can be any possible to produce by pressing into to a mould, said mould forming a polymeric product which can be flat or round or in between and where the three-dimensional shape can be any possible forming by pressing into a mould.

85. The method according to any of the claims 56-84, wherein the thickness of the polymeric product is between 0.001 and 40 cm thick, such as between 0.005 and 30 cm, preferable between 0.01 and 20 cm, more preferable between 0.02 and 10 cm, further preferable between 0.03 and 8 cm, yet further preferable between 0.04 and 5 cm, most preferable between 0.05 and 2 cm

86. An artificial cartilage product comprising a bio-compatible polymeric product with a layered structure, as defined in any of claims 1-48.

87. A prosthetic device comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

88. A hip endoprosthesis comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

89. A surface of a prosthetic device comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

90. A breast prosthesis comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

91. A stent comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

92. A catheter comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

93. A heart valve comprising a bio-compatible polymeric product with a layered structure as defined in any of claims 1-48.

94. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a medical device.

95. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a cartilage substitute.

96. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a prosthesis.

97. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a hip endoprosthesis.

98. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a breast prosthesis.

99. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a stent.

100. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a catheter.

101. Use of a bio-compatible polymeric product as defined in any of claim 1-48 for production of a heart valve.